

§ 52e.9

45 CFR part 74—Administration of grants
45 CFR part 75—Informal grant appeals procedures
45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments
45 CFR part 93—New restrictions on lobbying
51 FR 16958 or successor—NIH Guidelines for Research Involving Recombinant DNA Molecules
“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986), or successor
59 FR 14508 (as republished March 28, 1994), as may be amended, or its successor—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

[58 FR 54298, Oct. 21, 1993, as amended at 59 FR 59372, Nov. 17, 1994]

§ 52e.9 Additional conditions.

The Director, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Director's judgment those conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54299, Oct. 21, 1993]

42 CFR Ch. I (10–1–03 Edition)

PART 52h—SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351 (42 U.S.C. 289f-4); sec. 955(a), Pub. L. 97-35, 95 Stat. 590 (42 U.S.C. 300z-7(e)).

SOURCE: 43 FR 7862, Feb. 24, 1978, unless otherwise noted.

§ 52h.1 Applicability.

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. These regulations do not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

(b) Biomedical and behavioral research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of

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Health Professions, Health Resources and Services Administration.

(c) Applications for grants and contracts under section 2008 of the Act.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289f-4))

[45 FR 35328, May 27, 1980, as amended at 47 FR 50261, Nov. 5, 1982; 49 FR 38111, Sept. 27, 1984]

§ 52h.2 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Project period* has the same meaning as in 42 CFR part 52.

(c) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(d) *Awarding official* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated; *Except that*, where the Act specifically authorizes another official to make awards in connection with a particular program, the "awarding official" shall mean said other official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Peer review group* means a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications or contract projects in those fields.

(f) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(g) *Development* means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods.

(h) *Research and development contract project* means an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed to acquire new or fuller knowledge and understanding of

a subject and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods. The terms include (but are not limited to) development and utilization of resources, testing, demonstrations, clinical trials, preparation of reports, and production of experimental or test models necessary or incidental to a research and/or development activity, but exclude quantity production and routine product testing and quality control.

(i) *Project concept* means the basic purpose, scope, and objectives of the project.

(j) *Project approach* means the methodology to be followed and the resources needed in carrying out the project.

(k) *Contract proposal* means a written offer to enter into a contract, submitted to an awarding official by an individual or non-Federal organization, and including as a minimum a description of the nature, purpose, duration, and cost of the project and the methods, personnel, and facilities to be utilized in carrying it out.

(l) *Solicited contract proposal* has the same meaning as in 41 CFR 3-1.353(b)(2).

(m) *Unsolicited contract proposal* has the same meaning as in 41 CFR 3-4.5201.

(n) *Request for proposals* means a Government solicitation to prospective offerors, under procedures for negotiated contracts, to submit a proposal to fulfill specific agency requirements based on terms and conditions defined in the request for proposals. The request for proposals contains information sufficient to enable all offerors to prepare competitive proposals, and is as complete as possible with respect to: Nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements clauses, or other circumstances affecting the contract; format for cost proposals; and evaluation criteria by which the proposals will be evaluated.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act (5 U.S.C. App. I), Department of Health and